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In The United States Patent and Trademark Office

In re application of: James P. Elia

Serial No.: 10/791,648

Filed: March 2, 2004

For: TREATMENT FOR ARTHRITIS

Group No.: 1646

Examiner: Elizabeth C. Kemmerer

MAIL STOP FEE AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class mail, in an envelope addressed to Assistant Commissioner for Patents, MAIL STOP FEE AMENDMENT, P.O. Box 1450, Alexandria, VA 22313-1450 on

NOVEMBER 21, 2006

Gerald K. White 11/21/06
Signature Date of Signature

1. Transmitted herewith is a Supplemental Information Disclosure Statement, Form PTO 1449, and copies of the four (4) references, AF-AI, listed thereon.

2. **Fee Payment**

☒ Information contained in this Supplemental IDS was known to the undersigned attorney more than three (3) months prior to the filing of this statement; therefore, the filing fee under 37 C.F.R. 1.17(p) is enclosed.

Attached hereto is Check No. 1206 in the amount of \$ 180.00.

OR

☐ No fee is due.

Dated: November 21, 2006

Gerald K. White
Signature of attorney

Gerald K. White
Reg. No.: 26,611

GERALD K. WHITE & ASSOCIATES, P.C.
205 W. Randolph Street, Suite 835
Chicago, IL 60606
Phone: (312) 920-0588
Fax: (312) 920-0580
Email: gkwpatlaw@aol.com



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: James P. Elia)
Serial No.: 10/791,648) Group Art Unit: 1646
Filed: March 2, 2004) Examiner: Elizabeth C. Kemmerer
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The instant Supplemental Information Disclosure Statement is submitted to make of record four (4) publications.

The December 8, 2005 article in StemCellNews.com entitled, “5 Patients Get ‘New’ Knees in NUH Stem-Cell Trial” (Ref. AF) discloses a technique for the repair of damaged knees with autologous stem cells.

The August 2004 article in Arthritis & Rheumatism entitled, “Induction of Remission of Severe and Refractory Rheumatoid Arthritis by Allogeneic Mixed Chimerism” (Ref. AG) describes the successful allogeneic hematopoietic stem cell transplantation (HSCT) performed on a 52-year old woman. Please note the “Before and After” photographs A-D shown on page 2469.

The April 1, 2005 announcement by Osiris Therapeutics, Inc. (hereinafter “Osiris”) entitled, “Osiris Cleared by FDA to Begin Stem Cell Trial for Knee Repair” (Ref. AH) reported that the

Osiris received clearance from the U.S. Food and Drug Administration to begin stem cell trials for

repair of injured knee tissue. Note that the quotations of C. Randall Mills, Ph.D., President and CEO of Osiris, in the second paragraph of the announcement indicate that a large amount of research was performed prior to the FDA clearance. Note further in the last paragraph of the announcement, C. Thomas Vangsness, MD, Professor of Orthopedic Surgery at U.S.C.'s Keck School of Medicine and Chief of Sports Medicine at University Hospital, indicated that the evidence suggests that a simple injection of MSC's into the knee has the potential to regenerate healthy meniscus (emphasis added).


The April 25, 2006 announcement by Osiris entitled, "Osiris Completes Enrollment in Stem Cell Trial for Knee Repair" (Ref. AI) reported that Osiris completed enrollment in the first human clinical trial of stem cell therapy to repair tissue in the knee. Note, again, that another physician, Joel Boyd, MD, an orthopedic surgeon at TRIA Orthopaedic Research Institute, Minneapolis, Minnesota, stated that, "The ability to give patients a simple injection into the knee that could restore the meniscus and prevent the inevitable progression to osteoarthritis would be a significant advancement in the treatment of knee pain." (emphasis added).

Enclosed herewith, please find Form PTO-1449 (Modified) pertaining to the above-identified application. A copy of each publication listed thereon (References AF-AI) is enclosed.

An early action on the merits of the application is respectfully requested.

Respectfully submitted,

Date: November 21, 2006



Gerald K. White
Reg. No. 26,611

GERALD K. WHITE & ASSOCIATES, P.C.
205 W. Randolph Street, Suite 835
Chicago, IL 60606
Phone: (312) 920-0588
Fax: (312) 920-0580
Email: gkwpattlaw@aol.com

List of Patents and Publications For Applicant's Supplemental Information Disclosure Statement

Page 1 of 1



Form PTO-1449 (Modified)
(Use several sheets if necessary)

Docket No.: 1000-10-C5
Serial No.: 010/791,648
Filing Date: 03/02/04
Applicant: James P. Elia

Group No.: --- 1646
Examiner: - - - Elizabeth C. Kemmerer

Reference Designation U.S. PATENT DOCUMENTS								
Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)	

Foreign Patent Documents								
		Document Number	Date	Country	Class	Sub-Class	Translation Yes No	

Other Art (including author, title, date, pertinent pages, etc.)		
	AF	December 8, 2005, <u>StemCellNews.com</u> , "5 Patients Get 'New' Knees in NUH Stem-Cell Trial"
	AG	August 2004, <u>Arthritis & Rheumatism</u> entitled, "Induction of Remission of Severe and Refractory Rheumatoid Arthritis by Allogeneic Mixed Chimerism"
	AH	April 1, 2005 announcement, Osiris Therapeutics, Inc. entitled, "Osiris Cleared by FDA to Begin Stem Cell Trial for Knee Repair"
	AI	April 25, 2006 announcement, Osiris Therapeutics, Inc. entitled, "Osiris Completes Enrollment in Stem Cell Trial for Knee Repair"

Examiner	Date Considered
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.